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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Rupert Katritzky

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07/20/2010

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EXAMINER

MCCLELLAND, KIMBERLY KEIL

ART UNIT

PAPER NUMBER

1791

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/551,518	Applicant(s) KATRITZKY ET AL.	
	Examiner KIMBERLY K. MCCLELLAND	Art Unit 1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 74-128 is/are pending in the application.
- 4a) Of the above claim(s) 82-128 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 74-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/28/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. This application contains claims 82-128 drawn to an invention nonelected with traverse in the reply filed on 02/06/09. **A complete reply to the final rejection filed 12/29/09 must include cancellation of nonelected claims or other appropriate action** (37 CFR 1.144) See MPEP § 821.01.

Response to Amendment

Applicant is reminded they need to explicitly point out where support for all the newly claimed features comes from as required by MPEP 714.02 and 2163.06. See 37 CFR 1.111.

Drawings

In light of the current amendment, the previous objection to the drawings is withdrawn.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 77 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

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was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly amended claim language of the computer received an instruction appears to be new matter. The paragraphs cited by applicant do not disclose this feature. Clarification is required.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1 and 74-81 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: structural elements which enable application dependent upon the dimensions of the pack to be labeled. Clarification is required. Claims 74-81 are rejected due to dependency on independent claim 1.

6. Claims 1 and 74-81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Independent claim 1 requires the label applicator to apply labels "dependent upon the dimensions of the pack to be labeled" and in a "predetermined position, a predetermined orientation, or on a predetermined number of planes". It is unclear how the apparatus structure may be dependent upon its contents. It is also unclear how the label applicator is both dependent on the dimensions of the pack and instructed by a computer to place labels in a predetermined position. Does the label applicator function based on predetermined instructions, or

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based on the pack dimensions? It is unclear from the specification as filed what structure performs this function. Applicant has not specified what structure of the currently claimed apparatus performs this function. Clarification is required. Claims 74-81 are rejected due to dependency on independent claim 1.

7. As to claims 79-80, it is unclear how an apparatus may include a "remote" computer. Is the computer apart of the system or not? How may a portion of the system be remote from the system? What is the computer remote from?

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1 and 74-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,317,648 to Sleep et al. in view of U.S. Patent No. 6,036,812 to Williams et al.

10. With respect to claim 1, Sleep et al. discloses a labeling apparatus, including a feeder (26) a pharmaceutical pack, said means being arranged to deliver said pack to a labeling station (32/38/34), wherein said labeling station comprises a label printer (34) arranged to print a label comprising information specific to a patient for whom said pharmaceutical pack is intended, a label applicator (i.e. combined labelers; 38; column 10, lines 27-35) to apply said label to said pack, wherein the label is able to apply the

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label to the pack such that one or more of the position of the label on the pack, the orientation of the label relative to the pack, or the number of planes of the pack to which the label is applied, is dependent upon the dimensions of the pack to be labeled (column 10, lines 27-35); a computer (14) to enter an order for a pack and to pass information to the labeling station to instruct the label applicator to apply the label in a predetermined position, a predetermined orientation, or on a predetermined number of planes; and the system further comprising a delivery subsystem (i.e. output; column 10, lines 7-9) to deliver said pack from the labeling station so as to be accessible to a user. Sleep et al. does not specifically disclose the feeder is a robot arm.

11. Williams et al. discloses a pill dispensing system, including the use of a robot arm as a feeder (column 3, lines 60-65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the robot arm of Williams et al. with the feeder of Sleep et al. The motivation would have been to allow selective feeding of individual containers (column 3, lines 60-65).

12. Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. Ex parte Thibault, 164 USPQ 666, 667 (Bd. App. 1969). Consequently, the pharmaceutical packs and labels are not structurally limiting to the currently claimed apparatus.

13. The examiner would like to note that while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997);

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“[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original). A claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). Examiner notes the phrases “comprising information specific to a patient for whom said pharmaceutical pack is intended”, “so as to be accessible to a user”, “is able to apply the label to the pack such that one or more of the position of the label on the pack, the orientation of the label relative to the pack, or the number of planes of the pack to which the label is applied, is dependent upon the dimensions of the pack to be labeled”, and “to enter an order for a pack and to pass information to the labeling station to instruct the label applicator to apply the label in a predetermined position, a predetermined orientation, or on a predetermined number of planes” are drawn to the intended use of the currently claimed apparatus and do not further structurally define the apparatus. See MPEP § 2114.

14. As to claim 74, Sleep et al. discloses the apparatus is arranged such that the labeling station (38) applies the label in an orientation (column 10, lines 27-35) relative to the pack. The phrase, “which is dependent upon at least one dimension of the pack” is drawn to the contents of the apparatus and does not structurally contribute to the currently claimed apparatus.

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15. As to claim 75, Sleep et al. discloses the labeling station is arranged to orient the pack and label applicator (38) relative to one another (column 10, lines 27-35).

16. As to claim 76, Sleep et al. does not specifically disclose the label applicator is rotatable.

17. Williams et al. discloses a pill dispensing system, including discloses the label applicator is rotatable to adjust the label applicator's orientation (54; See Figure 9). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the rotatable label applicator of Williams et al. with the labeling applicator of Sleep et al. The motivation would have been to prevent wrinkles from forming during label application.

18. As to claim 77, Sleep et al. discloses the labeling station further comprises a computer (14; column 7, lines 6-9) to receive an instruction as to how the label is to be applied (column 10, lines 27-35).

19. As to claim 78, Sleep et al. discloses the label applicator is arranged to apply the label at a predetermined position on the pack (column 10, lines 27-35). The phrase "the position being variable from one pack type to another" is drawn to the contents of the apparatus and does not structurally contribute to the currently claimed apparatus.

20. As to claim 79, Sleep et al. discloses the apparatus includes a remote computer (14) to pass information to the labeling station to enable the label applicator to apply the label in the predetermined position (column 10, lines 27-35).

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21. As to claim 80, Sleep et al. discloses the apparatus includes a remote computer (14) to pass label positioning information directly to the labeling station or label applicator (column 10, lines 27-354).

22. As to claim 81, Sleep et al. discloses the apparatus includes labels of common size to all packs (column 10, lines 27-35).

23. Claims 1 and 74-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,672,356 to Jenkins et al. in view of U.S. Patent No. 6,036,812 to Williams et al.

24. With respect to claim 1, Jenkins et al. discloses a labeling system, including a feeder (10/12/20/28/30), said feeder being arranged to deliver said pack to a labeling station (38), wherein said labeling station comprises a label printer (122) arranged to print a label comprising information specific to a patient for whom said pack is intended, a label applicator (138) to apply said label to said pack, wherein the label is able to apply the label to the pack such that one or more of the position of the label on the pack, the orientation of the label relative to the pack, or the number of planes of the pack to which the label is applied, is dependent upon the dimensions of the pack to be labeled (column 9, lines 44-47; See Figures 1-8); a computer (44) to enter an order for a pack and to pass information to the labeling station to instruct the label applicator to apply the label in a predetermined position, a predetermined orientation, or on a predetermined number of planes; and the system further comprising a delivery subsystem (20/28) to deliver said pack from the labeling station so as to be accessible

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to a user (column 5, lines 2-17). Jenkins et al. does not specifically disclose the feeder is a robot arm.

25. Williams et al. discloses a pill dispensing system, including the use of a robot arm as a feeder (column 3, lines 60-65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the robot arm of Williams et al. with the feeder of Jenkins et al. The motivation would have been to allow selective feeding of individual containers (column 3, lines 60-65).

26. Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. Ex parte Thibault, 164 USPQ 666, 667 (Bd. App. 1969). Consequently, the pharmaceutical packs and labels are not structurally limiting to the currently claimed apparatus.

27. The examiner would like to note that while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997); “[A]pparatus claims cover what a device is, not what a device does.” Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original). A claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). Examiner notes the phrases “comprising information specific to a patient

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for whom said pharmaceutical pack is intended” and “so as to be accessible to a user” are drawn to the intended use of the currently claimed apparatus and do not further structurally define the apparatus. See MPEP § 2114.

28. As to claim 74, Jenkins et al. discloses the apparatus is arranged such that the labeling station (38) applies the label in an orientation (column 5, lines 2-17; column 9, lines 44-47) relative to the pack. The phrase, “which is dependent upon at least one dimension of the pack” is drawn to the contents of the apparatus and does not structurally contribute to the currently claimed apparatus.

29. As to claim 75, Jenkins et al. discloses the labeling station is arranged to orient the pack and label applicator (138) relative to one another (column 5, lines 2-17; column 9, lines 44-47).

30. As to claim 76, Jenkins et al. discloses the label applicator (138) is rotatable to adjust the label applicator’s orientation (Figures 5a-5b).

31. As to claim 77, Jenkins et al. discloses the labeling station further comprises a computer (44) to receive an instruction as to how the label is to be applied (column 9, lines 44-54).

32. As to claim 78, Jenkins et al. discloses the label applicator is arranged to apply the label at a predetermined position on the pack (column 5, lines 2-17; column 9, lines 44-47). The phrase “the position being variable from one pack type to another” is drawn to the contents of the apparatus and does not structurally contribute to the currently claimed apparatus.

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33. As to claim 79, Jenkins et al. discloses the apparatus further comprising a remote computer (44) to pass information to the labeling station to enable the label applicator to apply the label in the predetermined position (column 9, lines 44-54).

34. As to claim 80, Jenkins et al. discloses the apparatus further comprising a remote computer (44) to pass label positioning information directly to the labeling station or label applicator (column 9, lines 44-54).

35. As to claim 81, Jenkins et al. discloses the apparatus includes labels of common size for application to all packs (See Figures 2 and 2A).

Response to Arguments

36. This application contains claims 82-128 drawn to an invention nonelected with traverse in the reply filed on 02/06/09. **A complete reply to the final rejection filed 12/29/09 must include cancellation of nonelected claims or other appropriate action** (37 CFR 1.144) See MPEP § 821.01.

37. Applicant's arguments with respect to claims 1 and 74-81 have been considered but are moot in view of the new ground(s) of rejection. Applicant's remaining pertinent arguments are addressed below:

38. Applicant is reminded they need to explicitly point out where support for all the newly claimed features comes from as required by MPEP 714.02 and 2163.06. See 37 CFR 1.111.

39. With respect to applicant's arguments that "There is no suggestion in Sleep that this multi-branch system could be replaced by a single labeling station which adapts the

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application of a label based upon the dimension of the pack to be labeled.” examiner notes the multi branch system is treated as a single labeling station. Examiner notes the term “station” does not expressly limit the currently claimed apparatus to a single labeler. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a single labeler) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). As the multi branch labeler of Sleep is capable of altering the position and orientation of applied labels, it meets the currently claimed labeling station.

40. Examiner notes applicant argues that the phrase, “is able to apply the label to the pack such that one or more of the position of the label on the pack, the orientation of the label relative to the pack, or the number of planes of the pack to which the label is applied, is dependent upon the dimensions of the pack to be labeled” is structural, not functional. However, examiner notes no structure is disclosed in this phrase. Applicant has failed to identify any physical structure required by this claim language, but instead asserts that its intended operation is different from that of the prior art. Examiner notes the phrase is entirely drawn to the intended functional use of the apparatus. A claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. Ex

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parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). Consequently, this argument is not persuasive.

41. In response to applicant's argument that Jenkins does not disclose an "automated pharmaceutical dispensing system", examiner notes where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation. Rowe v. Dror, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997)

42. As to applicant's arguments that Jenkins discloses pallets, not packs, this argument is not persuasive. Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. Ex parte Thibault, 164 USPQ 666, 667 (Bd. App. 1969). The recited packs are considered contents of the apparatus, not structural components of the apparatus. Therefore, the packs are not found to be limiting to the currently claimed apparatus.

43. As to applicant's arguments that Jenkins discloses applying labels independently of pallet size, this argument is not persuasive. As noted above, the application of labels based on pack size is functional claim language, not structural. It is noted that the rejection is over apparatus claims not method claims. The prior art only has to provide a structure that is capable of performing in the manner claimed and not necessarily have ever been intended to be used in this manner. As such, apparatus claim 1 requires a robot arm, a label applicator CAPABLE of applying labels at different positions/orientations/planes, a computer, and a delivery system. It is the examiner's

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position that Jenkins in combination with Williams meets the limitations of the instant claims.

44. Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

Applicant's arguments are based solely on the lack of disclosure of the currently recited method steps in the prior art. However, claims 1 and 74-81 are drawn to an apparatus, not a method. Applicant repeatedly asserts such language is structural, without ever identifying any structural features. Examiner requests clarification as to what physical structure distinguishes the currently claimed apparatus over the cited prior art.

45. As to applicant's arguments that the phrase "depending on the dimensions of the pack to be labeled" imparts patentability to the claims, examiner disagrees.

Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. Ex parte Thibault, 164 USPQ 666, 667 (Bd. App. 1969). Consequently, the pharmaceutical packs and labels are not structurally limiting to the currently claimed apparatus. Furthermore, labelers are inherently structured to apply labels to packs with dimensions. If labelers are capable of applying labels at different positions/orientations for articles of varying sizes, then it is also CAPABLE of applying labels at different orientations/positions depending on article size, without altering the structure of the labeler.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to whose telephone number is (571)272-2372. The examiner can normally be reached on 8:00 a.m.-5 p.m. Mon-Thr.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Philip C. Tucker can be reached on (571)272-1095. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kimberly K McClelland/
Examiner, Art Unit 1791

KKM